

LISTING OF THE CLAIMS

1. (Currently Amended). An oral hydrophilic matrix formulation suitable for once-a-day administration comprising:

a. divalproex sodium, and;
b. said divalproex sodium is in admixture with a sufficient quantity of a pharmaceutically acceptable polymer, so that said formulation exhibits the following in-vitro dissolution profile, when measured in a type 2 dissolution apparatus (paddle) at 100 rpm, at a temperature of $37 \pm 0.5^\circ\text{C}$, in 500 ml of 0.1N HCl for 45 minutes, followed by 900 ml of 0.05 M phosphate buffer containing 75 mM sodium lauryl sulfate (pH 5.5) for the remainder of the testing period:

i. no more than about 30% of total valproate is released after 3 hours of measurement in said apparatus;
ii. from about 40 to about 70% of total valproate is released after 9 hours of measurement in said apparatus;
iii. from about 55 to about 95% of total valproate is released after 12 hour of measurement in said apparatus, and;
iv. not less than 85% of total valproate is released after 18 hours of measurement in said apparatus.

2. (Original). The formulation according to claim 1 in which said formulation exhibits the following in-vitro dissolution profile:

i. from about 15% to about 30% of total valproate is released after 3 hours of measurement in said apparatus;
ii. from about 40% to about 70% of total valproate is released after 9 hours of measurement in said apparatus;
iii. from about 55% to about 90% of total valproate is released after 12 hours of measurement in said apparatus, and;
iv. not less than 88% of total valproate is released after 18 hours of measurement in said apparatus.

3. (Original). The formulation according to claim 1 in which said formulation exhibits the following in-vitro dissolution profile:

- i. from about 15% to about 27% of total valproate is released after 3 hours of measurement in said apparatus;
- ii. from about 44% to about 69% of total valproate is released after 9 hours of measurement in said apparatus;
- iii. from about 59% to about 90% of total valproate is released after 12 hours of measurement in said apparatus, and;
- iv. not less than 88% of total valproate is released after 18 hours of measurement in said apparatus.

4. (Original). The formulation according to claim 1 in which said divalproex sodium is present in the amount of from about 40 to about 80 w/w % based upon the total weight of the formulation.

5. (Original). The formulation according to claim 3 in which said polymer is a water soluble hydrophilic polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and mixtures thereof.

6. (Original). The formulation according to claim 5 in which said divalproex sodium is present in the amount of from about 45 to about 65 w/w %, based upon the total weight of the formulation.

7. (Original). The formulation according to claim 6 in which said polymer is present in the amount of from about 20 to about 50 w/w %, based upon the total weight of the formulation.

8. (Original). The formulation according to claim 7 which further comprises one or more pharmaceutically acceptable excipients.

9. (Withdrawn). A method for treating migraine comprising administering a formulation according to claim 1 to a patient in need thereof.

10. (Original). A method for treating epilepsy comprising administering a formulation according to claim 1 to a patient in need thereof.

11. (Withdrawn). A method for treating bipolar disorders comprising administering a formulation according to claim 1 to a patient in need thereof.

12. (Original). The formulation according to claim 1, which when ingested orally produces a C_{\max} that is statistically significantly lower than the C_{\max} produced by a delayed release divalproex sodium tablet, when each is determined at steady state in a fasting population.

13. (Original). The formulation according to claim 12 which:

a) produces a C_{\min} that is not statistically significantly different from the C_{\min} produced by said delayed release divalproex sodium tablet, when each is determined at steady state in a fasting population, and;

b) said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each is determined at steady state in a fasting population.

14. (Currently Amended). An oral hydrophilic matrix formulation suitable for once-a-day administration comprising:

a. divalproex sodium, and;

b. said divalproex sodium is in admixture with a sufficient quantity of a pharmaceutically acceptable polymer, so that said formulation exhibits the following in-vitro dissolution profile, when measured in a type 2 dissolution apparatus (paddle) at 100 rpm, at a temperature of $37 \pm 0.5^\circ\text{C}$, in 500 ml of 0.1N HCl for 45 minutes, followed by 900 ml of 0.05 M phosphate buffer containing 75 mM sodium lauryl sulfate (pH 5.5) for the remainder of the testing period:

- i. from about 15% to about 27% of total valproate is released after 3 hours of measurement in said apparatus;
- ii. from about 44% to about 69% of total valproate is released after 9 hours of measurement in said apparatus;
- iii. from about 59% to about 90% of total valproate is released after 12 hours of measurement in said apparatus, and;
- iv. not less than 88% of total valproate is released after 18 hours of measurement in said apparatus.

15. (Original). The formulation according to claim 14, which when ingested orally produces a C_{\max} that is statistically significantly lower than the C_{\max} produced by a delayed release divalproex sodium tablet, when each is determined at steady state in a fasting population.

16. (Withdrawn). A hydrophilic matrix formulation suitable for once-a-day administration comprising:

- a) a valproate compound, and;
- b) said valproate compound is in admixture with a sufficient quantity of a pharmaceutically acceptable polymer, so that said formulation exhibits the following in-vitro dissolution profile, when measured in a type 2 dissolution apparatus (paddle) at 100 rpm, at a temperature of $37 \pm 0.5^{\circ}\text{C}$, in 500 ml of 0.1N HCl for 45 minutes, followed by 900 ml of 0.05 M phosphate buffer containing 75 mM sodium lauryl sulfate, pH 5.5, for the remainder of the testing period:
 - i. no more than about 30% of total valproate is released after 3 hours of measurement in said apparatus;
 - ii. from about 40 to about 70% of total valproate is released after 9 hours of measurement in said apparatus;
 - iii. from about 55 to about 95% of total valproate is released after 12 hours of measurement in said apparatus, and;
 - iv. not less than 85% of total valproate is released after 18 hours of measurement in said apparatus.

17. (Original). The formulation according to claim 1 in which said formulation exhibits the following in-vitro dissolution pattern:

- i. from about 15% to about 30% of total valproate is released after 3 hours of measurement in said apparatus;
- ii. from about 40% to about 70% of total valproate is released after 9 hours of measurement in said apparatus
- iii. from about 55% to about 90% of total valproate is released after 12 hours of measurement in said apparatus
- iv. not less than 88% of total valproate is released after 18 hours of measurement in said apparatus.

18. (Original). The formulation according to claim 1 in which said formulation exhibits the following in-vitro dissolution pattern:

- i. from about 15% to about 27% of total valproate is released after 3 hours of measurement in said apparatus;
- ii. from about 44% to about 69% of total valproate is released after 9 hours of measurement in said apparatus
- iii. from about 59% to about 90% of total valproate is released after 12 hours of measurement in said apparatus
- iv. not less than 88% of total valproate is released after 18 hours of measurement in said apparatus.

19. (Currently Amended). A method for the treatment of epilepsy in a patient in need thereof comprising:

- a) ~~the administration of~~ administering a single daily dose of at least one divalproex sodium formulation ~~of according to~~ claim 1 in which said daily dose is from 5% to 35% greater than the corresponding total daily dose that would be required for the patient consuming a delayed release divalproex sodium tablet administered twice-a-day, and;
- b) when said formulation is ingested orally said formulation produces:

i) a C_{\max} that is statistically significantly lower than the C_{\max} produced by the delayed release divalproex sodium tablet, when each is determined at steady state in a fasting population,

ii) a C_{\min} that is statistically significantly higher than the C_{\min} produced by said delayed release divalproex sodium tablet, when each C_{\max} is determined at steady state in a fasting population;

iii) an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each AUC is determined at steady state in a fasting population;

c) with the proviso that the ~~pharmacokinetic~~ pharmacokinetic comparison in (b) is based upon total daily doses that differ by a factor of from 5 to 30%, when compared on a milligram to milligram basis.

20. (Currently Amended). The method according to claim ~~22~~ 19 in which the total daily dose of said formulation is about 10% greater than the total daily dose of said delayed release divaproex sodium tablet.

21. (Original). The method according to claim 19 in which said patient consumes a formulation according to claim 13.